

§ 860.123 Reclassification petition: Content and form.

(a) Unless otherwise provided in writing by the Commissioner, any petition for reclassification of a device, regardless of the section of the act under which it is filed, shall include the following:

(1) A specification of the type of device for which reclassification is requested;

(2) A statement of the action requested by the petitioner, e.g., "It is requested that — device(s) be reclassified from class III to a class II";

(3) A completed supplemental data sheet applicable to the device for which reclassification is requested;

(4) A completed classification questionnaire applicable to the device for which reclassification is requested;

(5) A statement of the basis for disagreement with the present classification status of the device;

(6) A full statement of the reasons, together with supporting data satisfying the requirements of § 860.7, why the device should not be classified into its present classification and how the proposed classification will provide reasonable assurance of the safety and effectiveness of the device;

(7) Representative data and information known by the petitioner that are unfavorable to the petitioner's position;

(8) If the petition is based upon new information under section 513(e), 514(b), or 515(b) of the act, a summary of the new information;

(9) Copies of source documents from which new information used to support the petition has been obtained (attached as appendices to the petition).

(10) A financial certification or disclosure statement or both as required by part 54 of this chapter.

(b) Each petition submitted pursuant to this section shall be:

(1) Addressed to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Standards and Regulations (HFZ-84), 5600 Fishers Lane, Rockville, MD 20857;

(2) Marked clearly with the section of the act under which the petition is being submitted, i.e., "513(e)," "513(f)," "514(b)," "515(b)," or "520(l) Petition";

(3) Bound in a volume or volumes, where necessary; and

(4) Submitted in an original and two copies.

[43 FR 32993, July 28, 1978, as amended at 49 FR 14505, Apr. 12, 1984; 53 FR 11253, Apr. 6, 1988; 55 FR 11169, Mar. 27, 1990; 63 FR 5254, Feb. 2, 1998]

EFFECTIVE DATE NOTE: At 63 FR 5254, Feb. 2, 1998, § 860.123 was amended by adding new paragraph (a)(10), effective Feb. 2, 1999.

§ 860.125 Consultation with panels.

(a) When the Commissioner is required to refer a reclassification petition to a classification panel for its recommendation under § 860.134, or is required, or chooses, to consult with a panel concerning a reclassification petition, such as under § 860.130, § 860.132, or § 860.136, the Commissioner will distribute a copy of the petition, or its relevant portions, to each panel member and will consult with the panel in one of the following ways:

(1) Consultation by telephone with at least a majority of current voting panel members and, when possible, nonvoting panel members;

(2) Consultation by mail with at least a majority of current voting panel members and, when possible, nonvoting panel members; and

(3) Discussion at a panel meeting.

(b) The method of consultation chosen by the Commissioner will depend upon the importance and complexity of the subject matter involved and the time available for action. When time and circumstances permit, the Commissioner will consult with a panel through discussion at a panel meeting.

(c) When a petition is submitted under § 860.134 for a post-enactment, not substantially equivalent device ("new device"), in consulting with the panel the Commissioner will obtain a recommendation that includes the information described in § 860.84(d). In consulting with a panel about a petition submitted under § 860.130, § 860.132, or § 860.136, the Commissioner may or may not obtain a formal recommendation.